[redacted]

# P-18-0221

**Chemical Name:** [redacted]

**CASRN:** None

| ASSIGNMENTS | NAME | DATE |
|---|---|---|
| SAT Chair | Doritza Pagan-Rodriguez | 07/03/2018 |
| HH Hazard Assessor (A) | Amy Babcock | 07/03/2018 |
| HH Hazard QC Reviewer (A) | Susan Laessig | 07/10/2018 |
| HH Risk Assessor FOCUS (B) | Sailesh Surapureddi | 07-13-2018 |
| HH Risk QC Reviewer (B) | Keith Salazar | 07-19-18 |

| Human Health Report Status: | | DATE COMPLETED |
|---|---|---|
| X | HAZARD DRAFT- Pending Review | 07/06/2018 |
| X | HAZARD REVIEWED | 07/10/2018 |
| X | HAZARD FINAL | 07/11/2018 |
| X | RISK DRAFT- pending review | 07-15-2018 |
| x | RISK REVIEWED | 07-19-18 |
| X | RISK-FOCUS FINAL- Uploaded | 07-23-2018 |
| | POST-FOCUS UPDATE DRAFT | |
| | POST-FOCUS UPDATE FINAL- Uploaded | |

[redacted]

# 1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and other structural information. EPA concludes there is moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available quantitative and qualitative risk information, EPA concludes that there is risk for the PMN substance. The risk estimates for this chemical are for the intended conditions of use. Other conditions of use and their risks were not evaluated.

## 1.1 Hazard Summary

- Absorption of the high molecular weight fraction is nil all routes (pchem).
- Absorption of the low molecular weight fractions is good through the GI tract and poor to nil through the skin and lungs (pchem).
- Concern for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive, liver, and kidney toxicity based on the production of epoxides.
- Concern for sensitization based on allyl FGEW of 1142.
- Concern for kidney toxicity from the low molecular weight fractions based on maleic acid (hydrolysis product).
- Concern for chelation of nutrient metals leading to blood toxicity, developmental toxicity and other adverse effects based on the maleic acid moiety content [redacted]) may be mitigated by the expectation of rapid hydrolysis (water solubility is 1000 g/L).

## 1.2 Risk Summary

### 1.2.1 Workers

Risks were identified for workers for increased mortality, kidney damage, delayed growth via dermal exposure based on [redacted] of maleic acid released from the PMN degradation, MOE: 110, Benchmark MOE: 1000.

Potential risks were identified for workers for skin sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive, liver, and kidney toxicity hazard endpoints via dermal exposure based on the production of epoxides. Potential risks for these hazard endpoints were not quantified due to a lack of dose-response and due to a lack of suitable toxicity data for these hazards.

Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves.

Risks were not assessed for workers for inhalation exposures since exposures were expected to be negligible.

### 1.2.2 General Population

Risks were not identified for general population following inhalation exposures for increased mortality, kidney damage, delayed growth via stack air inhalation based on [redacted] maleic acid released from the PMN degradation, MOE: >1000s, Benchmark MOE: 1000.

[redacted]

Potential risks were not identified for general population for lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive, liver, and kidney toxicity hazard endpoints via stack air and drinking water exposure based on the production of epoxides. Based on estimated exposures of stack air releases with ADR as high as **8.64E-05 mg/kg/day** and LADD as high as **9.60E-07 mg/kg/day**, these exposure estimates are considered very low, and the very high allyl FGEW suggests that risks are unlikely

### 1.2.3 Consumers

Risks were not assessed because consumer exposures are not expected

## 1.3 Potentially Useful Information:

### 1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties.
Metabolism is assumed to be important based on NICNAS Assessment of an analog.
Metabolite is [redacted] of intact PMN.
There are no repeated dose data on the PMN substance itself.
Health effects are based on metabolite data.
The evaluation of the PMN is based on presumed metabolite.
Releases are below modeling threshold, therefore general population [ fugitive inhalation, drinking water, fish ingestion] were not quantified

### 1.3.2 Potentially Useful Information

Potentially useful information would inform understanding of absorption, the specific target organ toxicity, irritation, sensitization and developmental toxicity

[redacted]

# 2 HUMAN HEALTH HAZARD- PART A

## 2.1 Chemistry Summary

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| PMN: P-18-0221 | Submitter: Georgia-Pacific Chemicals LLC | | | | | Manu. | Import |
| Max. PV (KG): [redacted] | | | Binding Option Marked: | | | X | |
| MW: [redacted] | 33 | % < 500 | 66 | % <1000 | CASNO.: None | | |
| PMN Structure | | | | Prop. | Meas. | Est. | |
| [redacted] | | | | MP | | | |
| | | | | BP | | >400 | |
| | | | | Pres. | | at 760 mm Hg | |
| | | | | VP | | <0.000001 | |
| | | | | S-H2O | | 1000 | |
| | | | | log P | | -1.39 | |
| Chemical Name: [redacted] | | | | Analogs: [redacted] | | | |
| USE: Binder for manufacturing wood panels. A solution containing the PMN material is mixed with wood fibers; the coated wood fibers are then shaped into panels, pressed, and heat cured. This is a Sustainable Futures Submission. Allyl FGEW = 1142. | | | | [redacted] | | | |

## 2.1 SAT Summary

### 2.1.1 PMN Health Rating

2

P1-2 B3 T2

### 2.1.2 SAT Key Words

SENS, MUTA, ONCO, DEV, REPRO, LIVER, KIDNEY

### 2.1.3 Absorption

Absorption of the high molecular weight fraction (< 100) is nil all routes; absorption of the low molecular weight fractions (33% < 500 and 66% < 1000) is good through the GI tract and poor to nil through the skin and lungs (pchem).

[redacted]

### 2.1.4 SAT Health Summary

Expect oxidation of the terminal double bond via an epoxide intermediate. Concern for skin and lung sensitization, mutagenicity, oncogenicity, developmental toxicity, male reproductive, liver, and kidney toxicity based on the epoxide oxidation product. The substance is expected to be weak sensitizer based on allyl FGEW of 1142.

There is concern for kidney toxicity for the low molecular weight fractions (33% < 500 and 66% < 1000) based on maleic acid. A NICNAS Assessment for a polyalkyleneglycol maleinate substance concluded the polymer is expected to hydrolyze in biological systems to form maleic acid and the corresponding glycols. This assumption is reasonable for the PMN substance's LMW fractions based on high water solubility and estimated absorption.
Based on the maleic acid moiety content (53%) in the polymer, there is potential concern for blood toxicity, developmental toxicity and other adverse effects from the chelation of nutrient metals. However adverse effects from chelation may be mitigated under the assumption that hydrolysis of the polymer substance will be rapid (water solubility is 1000 g/L). For instance, the NICNAS Assessment for a polyalkyleneglycol maleinate substance did not consider this mode of action.

### 2.1.5 PMN Data (Study summary, POD)

This is sustainable futures submission. The submission concluded low concern for non-cancer and cancer effects based on TEST predictions, Tox Tree, Braga, Swiss ADME, and professional judgment.

The reference for the cited NICNAS assessment (see SAT Human Health Summary section above) is NICNAS Full public Report Polymer in Miralan HTP, 24 Feb 2005, File No:STD/1117.

The PMN substance is a polyanionic compound, but is not expected to fit the criteria for lung toxicity because it does not have a hydrophobic group and it has high water solubility.

### 2.1.6 Analog Data (analog, structure, study summary, POD)

No data available.

| CHEMISTRY REPORT ver. 04/98 | PAGE 5 | PMN: P-18-0221 |
|---|---|---|

(38) ANALOGS:

| PMN or CAS No. | Chem. Name | Structure | TSCA Y/N |
|---|---|---|---|
| [redacted] | | | N |
| | | | Y |

[redacted]

### 2.1.7 **Other Information** (SDS, structural alert or component of interest, basis, etc.)

## Section 2. Hazards identification

**OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**Classification of the substance or mixture** : ACUTE TOXICITY (oral) - Category 4
SKIN CORROSION - Category 1
SERIOUS EYE DAMAGE - Category 1
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (kidneys) - Category 2

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 50%

## Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

| Product/ingredient name | Result | Species | Dose | Exposure |
|---|---|---|---|---|
| Proprietary | LD50 Dermal | Rabbit | 11890 mg/kg | - |
| | LD50 Oral | Rat | 12000 mg/kg | - |
| Proprietary | LC50 Inhalation Vapor | Rat | >2.75 mg/l | 4 hours |
| | LD50 Dermal | Rat | >2000 mg/kg | - |
| | LD50 Oral | Rat | >2000 mg/kg | - |

Irritation/Corrosion

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|---|---|---|---|---|---|
| Proprietary | Eyes - Mild irritant | Rabbit | - | 50 milligrams | - |
| | Skin - Mild irritant | Human | - | 72 hours 112 milligrams Intermittent | - |
| | Skin - Mild irritant | Rabbit | - | 500 milligrams | - |

Carcinogenicity

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

| Name | Category | Route of exposure | Target organs |
|---|---|---|---|
| Proprietary | Category 2 | Oral | kidneys |

Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Routes of entry anticipated: Dermal, Inhalation.

Potential acute health effects

**Eye contact** : Causes serious eye damage.

**Inhalation** : No known significant effects or critical hazards.

**Skin contact** : Causes severe burns.

**Ingestion** : Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : Adverse symptoms may include the following:
pain
watering
redness

**Inhalation** : No specific data.

[redacted]

**Skin contact** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur

**Ingestion** : Adverse symptoms may include the following:
stomach pains

**Delayed and immediate effects and also chronic effects from short and long term exposure**

**Potential chronic health effects**

**General** : May cause damage to organs through prolonged or repeated exposure.

**Carcinogenicity** : No known significant effects or critical hazards.

**Mutagenicity** : No known significant effects or critical hazards.

**Teratogenicity** : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects** : No known significant effects or critical hazards.

**Numerical measures of toxicity**

**Acute toxicity estimates**

| Route | ATE value |
|---|---|
| Oral<br>Inhalation (vapors) | 625 mg/kg<br>37.5 mg/l |

### 2.1.8 Exposure Routes of Interest

[

| | Route of Interest |
|---|---|
| X | Inhalation |
| X | Dermal |
| X | Ingestion |

## 2.2 Human Health Category (From US EPA 2010 document)

**Chemical Category:** Esters (Eco only)
**Chemical Category Health Concerns:** N/A
**Category Testing Strategy:** N/A

## 2.3 Point of Departure Selected and Basis

No POD identified for the intact PMN substance. PODs below are for maleic acid, which is 53% of the PMN substance.

### 2.3.1 POD for Inhalation Exposure

**POD type:** LOAEC
**POD Value:** 720 $mg/m^3$
**POD Chemical:** Maleic acid
**POD Route:** Inhalation
**POD Hazard Endpoint:** Kidney effects
**POD Basis:** Lowest data point reported
**POD Benchmark MOE:** 1000
**Reference:** IUCLID as cited in HSDB file for Maleic Acid

[redacted]

### 2.3.2 POD from 2-year Rodent (male rat) Study

**POD type:** LOAEL
**POD Value:** 250 mg/kg/d
**POD Chemical:** Maleic acid
**POD Route:** Oral
**POD Hazard Endpoint:** Increased mortality, kidney damage, delayed growth
**POD Basis:** Lowest dose tested
**POD Benchmark MOE:** 1000
**Reference:** IUCLID as cited in HSDB file for Maleic Acid

[redacted]

# 3 HUMAN HEALTH RISK (PART B)

## 3.1 USES and EXPOSURES

### 3.1.1 Uses

Binder for manufacturing wood panels. A solution containing the PMN material is mixed with wood fibers; the coated wood fibers are then shaped into panels, pressed, and heat cured. Allyl FGEW = 1142.

### 3.1.2 Worker Exposure

#### 3.1.2.1 Inhalation

negligible (VP < 0.001 torr)
negligible (VP < 0.001 torr)

#### 3.1.2.2 Dermal

Exposure to Liquid at [redacted] concentration
Potential Dose Rate: [redacted] mg/day over 250 days/yr; Basis: Loading Liquid Product into Tank Trucks
Exposure to Liquid at [redacted] concentration
Potential Dose Rate: [redacted] mg/day over 250 days/yr; Basis: Sampling Liquids

Exposure to Liquid at [redacted] concentration
Potential Dose Rate: [redacted] mg/day over 250 days/yr; Basis: Unloading Liquid Raw Material from Tank Trucks

### 3.1.3 General Population Exposure:

#### 3.1.3.1 Drinking Water

Groundwater ingestion (from landfill leaching) with LADD as high as **1.94E-03 mg/kg/day**

#### 3.1.3.2 Fish

No releases to surface water.

#### 3.1.3.3 Air/Inhalation

Inhalation from incineration releases with ADR as high as **8.64E-05 mg/kg/day** and LADD as high as **9.60E-07 mg/kg/day**

[redacted]

| Exposure Scenario | Water | | | | | | Land fill(non-sludge) | Stack | | Fugitive | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Release Activity(ies) exposure Calculations | Drinking Water | | Fish Ingestion | | | | | | | | |
| | ADR mg/kg/day | LADD mg/kg/day | ADR mg/kg/day | LADD mg/kg/day | 7Q10cc 1000 ug/l | PDM Exceeded # Days | LADD mg/kg/day | ADR mg/kg/day | LADD mg/kg/day | ADR mg/kg/day | LADD mg/kg/day |
| MFG:Max ADR | -- | -- | -- | -- | -- | -- | -- | 1.23e-5 (6.74e-2) | -- (--) | -- (--) | -- (--) |
| MFG:Max LADD | -- | -- | -- | -- | -- | -- | 1.94e-3 | -- (--) | 7.82e-7 (1.01e-2) | -- (--) | -- (--) |
| USE:Max ADR | -- | -- | -- | -- | -- | -- | -- | 8.64e-5 (4.70e-1) | -- (--) | -- (--) | -- (--) |
| USE:Max LADD | -- | -- | -- | -- | -- | -- | 6.90e-6 | -- (--) | 9.60e-7 (1.24e-2) | -- (--) | -- (--) |

### 3.1.4 Consumer Exposure

No identified consumer exposures

## 3.2 RISK CALCULATIONS

### 3.2.1 Worker Calculations

**Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR**

| | Animal or Human | | | Human | | | | | | | Benchmark MOE | Endpoint Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/day Potential Dose Rate (PDR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Body Weight kg | Exposure mg/kg-day | Structural Alert as % of PMN | Margin of Exposure MOE | 1000 | LOAEL |
| Dermal | 2.5E+02 | 5 | 100% | 1.3E+03 | 5 | 15% | 80 | 1.6E+01 | 53% | **193.5** | | |

Risks were identified for workers for increased mortality, kidney damage, delayed growth based on 53% of maleic acid released from the PMN degradation, MOE: 194, Benchmark MOE: 1000.

[redacted]

### 3.2.2 General Population Calculations

**Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR**

| | Animal or Human | | | Human | | | | | | Benchmark MOE | Endpoint Type |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Route | POD mg/kg-day | POD Exposure Duration Days/Wk | POD Route % Absorp | Exposure mg/kg-day Acute Dose Rate (ADR) | Exposure Duration Days/Wk | Exposure Route % Absorp | Multiplier for Susceptible Subpopulations | Structural Alert as % of PMN | Margin of Exposure MOE | 1000 | LOAEL |
| Stack Air Inhalation | 2 5E+02 | 5 | 100% | 8.6E-05 | 5 | 100% | 1.0 | 53% | **5,459,468.90** | | |

**General Population Margin of Exposure (MOE) Calculations using inhalation POD and Engineering Report PDR**

| | Animal or Human POD | | | Population Exposure | | | | | | Benchmark MOE | Endpoint Type |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Inhalation Exposure Scenario | POD Conc. $mg/m^3$ | POD Period hrs/day | POD Duration days/wk | Exposure (24-hr conc.) (ug/m3) | Population Exposure Duration Hours/Day | Exposure Duration Days/Wk | Structural Alert as % of PMN | POD Conc - Duration Correction - $Scenario_{HEC}$ $mg/m^3$ | **Margin of Exposure MOE** | 1000 | LOAEL |
| Stack air | 7.2E+02 | 6.00 | 7 | 4.7E-01 | 24.00 | 5 | 53% | 2.5E+02 | **1.0E+06** | | |

Risks were not identified for general population for increased mortality, kidney damage, delayed growth based on 53% of maleic acid released from the PMN degradation, MOE: >1000, Benchmark MOE: 1000.

### 3.2.3 Consumer Calculations

Risks were not assessed because consumer exposures are not expected